



K130764

APR 26 2013

510(k) Notification
Audit® MicroCV™ Vitamin D Linearity Set

510(k) Summary

A. Submitter

Aalto Scientific, Ltd.
1959 Kellogg Ave.
Carlsbad, CA 92008
Telephone: (760) 431-7922
Fax: (760) 431-6824

B. Contact Person

Dessi Lyakov
Regulatory Affairs Manager
Telephone: (760) 431-7922 Ext. 118
E-mail: dlyakov@aaltoscientific.com

C. Date of Summary Preparation

February 15, 2013

D. Device Identification

Product Trade Name: Audit® MicroCV™ Vitamin D Linearity Set
Common Name: Vitamin D Linearity
Classification Name: Assay QC Material
Device Classification: Class I, reserved
Regulation Number: 21 CFR 862.1660
Panel: 75
Product Code: JJX
Device to Which Substantial Equivalence is Claimed
Product Trade Name: Audit® MicroCV™ hs-CRP Linearity Set
Aalto Scientific, Ltd., Carlsbad, CA
K101427

E. Description of the Device

The Audit® MicroCV™ Vitamin D Linearity Set is an assayed quality control material consisting of five levels of human and equine based serum, with each level containing Vitamin D. It is used to confirm the proper calibration, linear operating range, and reportable range of Vitamin D. Level A is near the lower limit level and Level E has concentrations near the upper limit of instruments. Levels B – D are related by linear dilution of Level A and Level E.

F. Statement of Intended Use

The Audit® MicroCV™ Vitamin D Linearity Set is an assayed quality control material consisting of five levels of human and equine based serum. Each level contains Vitamin D. These five levels demonstrate a linear relationship to each other for Vitamin D. It is intended to simulate human patient serum samples for purpose of determining linearity, calibration



510(k) Notification Audit® MicroCV™ Vitamin D Linearity Set

verification and verification of reportable range for Vitamin D.

The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling and may be used as quality control material for Vitamin D. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The Audit® MicroCV™ Vitamin D Linearity Set should not be used for calibration or standardization of the Vitamin D assay. The Audit® MicroCV™ Vitamin D Linearity Set is "For In Vitro Diagnostic Use Only".

G. Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Audit® MicroCV™ Vitamin D Linearity Set. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

Open Vial Stability: Once a vial has been opened, the Vitamin D will be stable for 30 days when stored tightly capped at 2 - 8° C.

Shelf Life: Two years, when stored unopened at 2 - 8° C.

Note: Real time studies are ongoing to support the shelf life of this product.

H. Expected Values

Value assignment of Audit® MicroCV™ Vitamin D Linearity Set have been performed to determine the expected values of Vitamin D analyte. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

Vitamin D, ng/mL, Instrument: Advia Centaur, Siemens Reagent									
Level A		Level B		Level C		Level D		Level E	
Target value	Target Range	Target value	Target Range	Target value	Target Range	Target value	Target Range	Target value	Target Range
20.18	17.15-23.21	46.57	39.58-53.55	77.68	66.03-89.33	107.32	91.22-123.42	135.72	115.36-156.08



510(k) Notification

Audit® MicroCV™ Vitamin D Linearity Set

I. Technical Characteristics Compared to Predicate Device

Characteristics	Audit® MicroCV™ Vitamin D Linearity Set (New)	Audit™ MicroCV™ hs-CRP Linearity Set (K101427)
Intended Use	<p>The Audit® MicroCV™ Vitamin D Linearity Set is an assayed quality control material consisting of five levels of human and equine based serum. Each level contains Vitamin D. These five levels demonstrate a linear relationship to each other for Vitamin D. It is intended to simulate human patient serum samples for purpose of determining linearity, calibration verification and verification of reportable range for Vitamin D.</p> <p>The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling and may be used as quality control material for Vitamin D. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The Audit® MicroCV™ Vitamin D Linearity Set should not be used for calibration or standardization of the Vitamin D assay. The Audit® MicroCV™ Vitamin D Linearity Set is "For In Vitro Diagnostic Use Only".</p>	<p>The Audit™ MicroCV™ hs-CRP Linearity Set is assayed quality control material consisting of five levels human based serum. Each level contains High Sensitivity C-Reactive Protein (hs -CRP) analyte. The five levels demonstrate a linear relationship to each other for High Sensitivity C-Reactive Protein (hs -CRP) analyte. It is intended to simulate human patient serum samples for purpose of monitoring and detecting systematic analytical deviations of laboratory testing procedures for High Sensitivity C-Reactive Protein (hs -CRP). This product may be used as quality control material for High Sensitivity C-Reactive Protein (hs -CRP) analyte. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Audit™ MicroCV™ hs-CRP Linearity Set is "For In Vitro Diagnostic Use Only".</p>
Number of Analytes per vial	1	1
Number of levels per set	5	5
Contents	5 x 2 mL	5 x 1 mL
Matrix	Human and Equine Based Serum	Human Based Serum
Type of Analytes	Vitamin D	High Sensitivity C-Reactive Protein
Form	Liquid	Liquid
Storage	2 to 8° C Until expiration date	2 to 8° C Until expiration date
Open Vial Stability	30 days at 2 to 8° C	20 days at 2 to 8° C

J. Conclusions

Based upon the purpose of the device, the descriptions and labeling of the predicate device, the safety and efficacy, and the stability data generated, the product is substantially equivalent to the predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 26, 2013

Aalto Scientific, Ltd.
C/O Dessi Lyakov
1959 Kellogg Ave.
CARLSBAD CA 92008

Re: K130764

Trade/Device Name: Audit@ MicroCV™ Vitamin D Linearity Set

Regulation Number: 21 CFR 862.1660

Regulation Name: Quality control material

Regulatory Class: I

Product Code: JJX

Dated: March 19, 2013

Received: March 29, 2013

Dear Dessi Lyakov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number

(800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carol  Benson -S for

Courtney H. Lias, Ph.D.

Director

Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k130764

Device Name: Audit® MicroCV™ Vitamin D Linearity Set

Indications For Use:

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The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling and may be used as quality control material for Vitamin D. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The Audit® MicroCV™ Vitamin D Linearity Set should not be used for calibration or standardization of the Vitamin D assay. The Audit® MicroCV™ Vitamin D Linearity Set is "For In Vitro Diagnostic Use Only".

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Phan -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k130764